INTRODUCTION

The Voluntary Scrapie Flock Certification Program is designed to monitor flocks and certify the Scrapie status of the animals that are enrolled in the program. Any sheep or goat owner or manager may apply to participate in the Voluntary Scrapie Flock Certification Program.

This document outlines the Voluntary Scrapie Flock Certification Program Standards and was approved by the Deputy Administrator of the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services on October 17, 1997.

I. DEFINITIONS

The following definitions cover the Voluntary Scrapie Flock Certification Program Standards and are superseded by any definitions pertaining to scrapie that are published in Title 9, Code of Federal Regulations, Parts 54 and 79.

Accredited veterinarian	A veterinarian approved by the Administrator of APHIS, USDA, in accordance with Title 9, Code of Federal Regulations, Part 161, to perform functions required by cooperative State-Federal animal disease control and eradication programs.
Administrator	The Administrator of APHIS, USDA, or any other official to whom the Administrator has delegated authority to act in his or her stead.
Animal	Any sheep or goat.
APHIS	The Animal and Plant Health Inspection Service, United States Department of Agriculture.
Area Veterinarian in Charge (AVIC)	The veterinary official of Veterinary Services, APHIS, United States Department of Agriculture, who the Administrator assigned to supervise and perform official animal health work in a State(s).
Breed Associations and Registries	Organizations maintaining the animals' permanent records of ancestry or pedigrees, individual animal identification and ownership.
Board	The State Scrapie Certification Board.
Certified Flock	A Complete Monitored category flock that has been participating in the program and has met the provisions of Section III for 5 years or more.

Commingling	Animals grouped together having physical contact. Commingling does not include limited contacts. Examples of commingling include concurrently sharing the same section in a transportation unit where there is uninhibited physical contact.
Deputy Administrator	The Deputy Administrator for Veterinary Services, APHIS, United States Department of Agriculture, or any other official to whom the Deputy Administrator has delegated authority to act in his or her stead.
Enrolled Flock	A Complete Monitored Category Flock that has been participating in the program but has not yet met the criteria for certified status.
Enrollment Date	The date on which the State Scrapie Certification Board gave final approval for initial program participation.
Exposed Animal	Any animal which has been in the same flock at the same time within the previous 60 months as a scrapie positive animal, excluding limited contacts.
Exposed Flock	A flock that had contained, within the previous 60 months, an animal which was later confirmed as scrapie positive in another flock. The flock will be classified as exposed until the diagnostic sampling requirements of Section IV have been met.
Flock Category	Classification of a flock with regard to scrapie or the Voluntary Scrapie Flock Certification Program. The possible categories include: ·Complete Monitored (ENROLLED, CERTIFIED) ·Selective Monitored (SELECT) ·Exposed ·Infected ·Source ·Trace
Flock/herd	All animals maintained on a single premise which are commingled; and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Two flocks may be maintained on a single premise if they: 1. are kept 30 feet apart by a double fence at all times while on the premise. 2. have flocks records and identification which are separate.

	3. have separate lambing facilities, including buildings and pastures (e.g. if lambing occurs on a pasture type situation, the pasture used to lamb out one flock may not be used by the other flock at any time). 4. do not share equipment between the flocks without prior cleaning and disinfection (see Appendix II). This document will use the term "flock" in reference to groups of animals.
Infected Flock	Any flock in which an APHIS representative or State animal health official has determined an animal to be scrapie-positive. A flock will no longer be considered an infected flock after it has completed the requirements of 9 CFR, Part 79.
Limited Contact	Contacts between animals off of the flock's premises at fairs, shows, exhibitions and sales, ewes to be inseminated, flushed, or implanted, and for rams at ram test or collection stations, and not during or up to 60 days after lambing/kidding. Limited contacts do not include commingling or transportation to other flocks for the purposes of breeding, except as allowed by program standards. Examples of limited contacts include, incidental contact in the show/sales ring (see Appendix III).
National Scrapie Oversight Committee	A national committee composed of Industry, State, and Federal representatives which gives guidance to APHIS on the policies and practices of the Voluntary Scrapie Flock Certification Program.
Nonparticipating Flock	A flock that is not enrolled in the Voluntary Scrapie Flock Certification Program.
Official Identification	A unique individual identification which meets the following criteria: ·permanent ·secure ·unique numbers from a central repository ·traceable The types of identification approved for the Voluntary Scrapie Flock Certification Program are: ·Tamper-resistant Ear tag approved by APHIS for use in the Voluntary Scrapie Flock Certification Program ·Flank or Ear Tattoo ·Electronic Identification

Official Laboratory	A laboratory designated by a State and approved by the Administrator to perform the Program-required scrapie diagnostic procedures. The National Veterinary Services Laboratory, United States Department of Agriculture, Ames, Iowa, is the reference laboratory for diagnostic procedures.
Owner	An individual, partnership, company, corporation, or other legal entity which has legal or rightful title to a flock of animals, regardless of any liens held on the animals or flock.
Premises	The ground, area, buildings, and equipment occupied by one or more flocks of animals.
Program	The Voluntary Scrapie Flock Certification Program (VSFCP)
Scrapie	A nonfebrile, transmissible, insidious, degenerative disease affecting the central nervous system of sheep and goats. Scrapie, a transmissible spongiform encephalopathy, may cause, but is not limited to, the following signs in affected animals: ·weight loss despite retention of appetite ·behavioral abnormalities ·pruritus (itching) ·wool pulling ·biting at legs or side ·lip smacking ·motor abnormalities such as incoordination ·high stepping gait of forelimbs ·bunny hop movement of rear legs ·blindness ·swaying of back end ·increased sensitivity to noise and sudden movement ·tremor ·“star gazing" ·head pressing ·recumbency It is important to note that not all Scrapie-affected animals show all clinical signs.
Scrapie-positive Animal	An animal which has had a diagnosis of scrapie confirmed through tests by an official laboratory.
Scrapie Suspect	An animal which displays clinical signs suggestive of scrapie.

Source Flock	A flock in which a Veterinary Services representative has determined that at least two animals, that were diagnosed as Scrapie-positive animals at an age of 54 months or less, were born. In order to be a source flock, the second Scrapie-positive diagnosis must be made within 60 months of the first Scrapie-positive diagnosis. A flock will no longer be considered a source flock after it has completed the requirements of 9 CFR, Part 79.
State Animal Health Official	A State or State political subdivision-employee working in animal health activities authorized to perform Voluntary Scrapie Flock Certification Program duties.
Status	The classification of a flock participating in the Complete Monitored Category. Enrolled Status is given to flocks that are approved to participate in the Complete Monitored Category. After the flock has successfully met all program requirements for five continuous years, the flock will be eligible for certified status.
Status Date	Initially, the Status date is equivalent to the Enrollment Date and is issued as the Month and Year of initial program participation (i.e., April 1998). If the flock continues to meet all Program standards the Status Date will not change. For flocks that acquire animals or commingle with animals that do not meet Program standards under Section III, the Status Date would change to the date (Month and Year) the non-enrolled animals are acquired or commingled OR to the Status Date of the flock with the most recent Status Date for animals commingled/acquired from an enrolled flock.
Trace Flock	A flock in which an APHIS representative or a State representative has determined that one animal was born that was diagnosed as a Scrapie-positive animal at an age of 54 months or less.
Veterinary Services Representative	An individual employed by Veterinary Services, APHIS, in animal health activities who the Administrator authorized to perform Voluntary Scrapie Flock Certification Program duties.
Voluntary Scrapie Flock Certification Program	A voluntary State/Federal/Industry Cooperative effort established and maintained to: 1. reduce scrapie's occurrence and spread; 2. identify flocks which have been free of evidence of scrapie over specified time periods; 3. contribute to the eventual eradication of Scrapie.

II. ADMINISTRATIVE PROCEDURES

A. Oversight of the Voluntary Scrapie Flock Certification Program

The National Scrapie Oversight Committee will be appointed by APHIS from recommendations made by the following groups:

- ·Animal Producers;
- ·Allied Industry;
- ·APHIS;
- ·State Animal Health Officials;
- ·Accredited Veterinarians; and
- ·Animal Breed Registries and Associations.

Priority for committee membership will be given to producers enrolled in the program. The committee reviews the Voluntary Scrapie Flock Certification Program and makes individual recommendations to the Deputy Administrator regarding policy and technical improvements in the Certification Program.

The Committee will meet at least once a year, consult with scientific and technical experts, consider Program improvement suggestions, and support the Program at national, State, and local sheep events and in the sheep-producing community.

B. State Scrapie Certification Board

A State Scrapie Certification Board will be formed within each State to:

- ·Administer the Voluntary Scrapie Flock Certification Program;
- ·Review Program enrollment applications and status advancement;
- ·Review situations which may result in a reduction of certification status or dismissal from the Program;
- ·Educate producers regarding scrapie.

The State Scrapie Certification Board will be comprised of

- ·APHIS' Area Veterinarian-in-charge,
- ·Animal Producers,
- ·Accredited Veterinarians, and
- ·State animal health official in cooperating States.

State Certification Boards should:

·be chaired by an enrolled producer;
·encourage Board members who own sheep to be enrolled in the program
·support the program at State and Local sheep events and in the sheep-producing community; and
·meet at least annually.

The Area Veterinarian-in-charge, in cooperation with the State animal health official and flock owners will appoint members to the State Scrapie Certification Board. Boards may delegate their authority to subcommittees and may enact more stringent requirements to fit their State's scrapie situation.

C. Duties of Program Participants

1) APHIS

APHIS will maintain a records database for use in the Program.

APHIS, in cooperation with State animal health agencies and accredited veterinarians, will perform inspections, provide guidance and education, and collect and submit diagnostic samples in accordance with Appendix I.

2) PRODUCERS

·establish and maintain records;
·make animals and records available for inspection by State or Federal Animal Health Officials and State Scrapie Certification Board representatives, given reasonable prior notice;
·authorize access to records maintained by breed associations, registries, livestock markets, and packers;
·identify animals with official identification as specified by the Program standards;
·allow State, Federal, or State Scrapie Certification Board representatives to enter premises to carry out Program procedures;
·have the necessary facilities and personnel available to assist in the inspection of animals and animal records;
·report scrapie suspect animals to a State animal health official, APHIS representative, or an accredited veterinarian; and
·ensure that tissue samples are collected and submitted for diagnostic purposes as specified by Program standards.
·report acquisitions of lower Status or nonparticipating animals in accordance with Section III.

3) BREED REGISTRIES AND ASSOCIATIONS, LIVESTOCK MARKETS AND PACKERS

·Maintain liaison with flock owners;
·Assist in providing flock owners with information on the Voluntary Scrapie Flock Certification Program;
·Facilitate the information exchange regarding transfer of animals; and
·Encourage information reporting between flock owners, State animal health agencies, and APHIS**.**

D. Application for Program Status

1) ENTRY INTO THE PROGRAM:

The State Scrapie Certification board will review enrollment applications within 60 days of the receipt of the application package. The Status Date, for initial flock enrollment, is date the State Board approves the application for entry into the Program. The application package includes:

·a completed Program application;
·a list of animals in the flock including at least official identification numbers, breed, and sex information as specified by the certification category applied for;
·statement by an accredited veterinarian (if available) declaring that the flock free of Scrapie to the best of his/her knowledge (If an accredited veterinarian is not available, this statement can be made by a State or Federal veterinarian.); and
·an inspection report by an authorized State or Federal regulatory official, including verification of the information provided on the application by the flock owner and verification of the official identification of each animal listed in the application.

State or Federal Animal Health Officials will provide each enrolling Program participant and their accredited veterinarian, with an educational scrapie review.

Once a flock is approved to enter the program, it will be issued an Enrollment Date. This date will serve as the Status Date until the flock fails to meet all Program standards under Section III. For flocks that acquire animals or commingle with animals that do not meet Program standards under Section III, the Status Date would change to the date the non-enrolled animals are acquired or commingled, or to the Status Date of the flock with the most recent Status Date for animals from enrolled flocks. The Enrollment Date would not change.

2) ADVANCEMENT TO HIGHER STATUS

When a flock has obtained a Status Date that is over five years old (that is, it has met all of the program standards and has not acquired animals or commingled with unapproved animals), it may apply to advance to Certified Status. The State Scrapie Certification board will review advancement applications for movement from Enrolled Status to Certified Status within 60 days of the receipt of the application package. The application package includes:

·a completed Program advancement application;
·a list of animals in the flock including official identification numbers, breed, and sex information and additional information required on acquired and natural additions as specified in III A 2 d;
·statement by an accredited veterinarian declaring that to the best of their knowledge, there has been no evidence of scrapie in the flock since the Status Date; and
·an inspection report by a State or Federal regulatory official, including verification of the information provided on the application by the flock owner and verification of the official identification of each animal listed in the application.

a) FLOCKS MEETING ALL REQUIREMENTS DURING A YEAR AT CURRENT STATUS

During the annual inspection, a flock's Status Date would be maintained if:

- scrapie has not been diagnosed in the flock and it has not been deemed a source flock since its enrollment,
-the minimal requirements for the Status currently held by a flock have been fulfilled, and
-the flock has only had acquisitions or commingling of animals approved for the current Status.

b) FLOCKS NOT MEETING ALL REQUIREMENTS AT CURRENT STATUS

If , during the year at the current Status, a flock has:

- not met the minimum requirements for the Status currently held and/or
- has acquired or commingled animals in the flock that did not meet the requirements of the current status,

then the flock's Status Date will convert to the date when the flock was brought back into program compliance, or the Status Date of the acquired or commingled animals.

E. Downgrading of Certification Status

If an enrolled or certified flock has a confirmed diagnosis of scrapie in the flock or an epidemiologic investigation reveals it to be a source flock, the flock will be removed from the Program. The removed flock may reapply for enrollment in the Program after the flock has completed the requirements set forth in 9CFR, Part 79 for infected or source flocks.

If a Certified Flock acquires ewes or commingles with ewes that are not from a Certified Flock, the Status of the flock will be lowered to Enrolled and it's Status Date will change. If an Enrolled Flock acquires ewes or commingles with ewes from a non-participating flock or from a flock with a more recent Status Date, it will continue with Enrolled Status but the Status Date will change. After acquiring or commingling with ewes from non-participating flocks, the receiving flock's Status Date will become the date that the ewes were acquired or commingled.

After acquiring or commingling with ewes from enrolled flocks with a more recent Status Date, the Status Date of the receiving flock will become the most recent Status Date of the flocks involved.

For Certified Flocks, if rams are acquired from non-participating flocks, the Status of a Certified flock will be lowered to Enrolled Status with a status Date 4-years prior to the date of acquisition. Therefore, this flock would have Enrolled Status with one year left until an application for Certified Status would be considered. For Certified flocks, if rams are acquired from Enrolled flocks and do not meet the requirements in III A5a, the flock Status will be lowered to Enrolled Status and it's Status Date will change. For Certified and Enrolled flocks, if rams are acquired from enrolled flocks and do not meet the requirements in III A5a, the Status Date of the receiving flock will be changed to the most recent Status Date of the flocks involved. For Enrolled flocks, if rams are acquired from non-participating flocks and do not meet the requirements in III A5a, the receiving flock's Status Date will change to the date of acquisition or commingling. See section III A 7 for germplasm acquisitions.

The State Scrapie Certification Board shall recommend to downgrade a participating flock's status or remove it from the Program if its owner or manager has not complied with the standards, unless a compelling argument, based upon sound scientific principals, can be presented. A flock may reenter the Program after fulfilling Board-determined requirements.

F. Appeal

APHIS will notify a flock owner that their flock is being considered for reduction in Status or removal from the Program by the State Scrapie Board. The State Board will give the affected flock owner an opportunity to present his or her views to the Board before the Board makes its final recommendation about reduction or removal. APHIS will decide on the Status of the flock, based upon the Board's recommendation and notify the flock owner of the decision. The flock owner may appeal to the Administrator within 30 days after notification of the Board's recommendation.

III. PROGRAM REQUIREMENTS

A. COMPLETE MONITORED CATEGORY

1) PROGRAM STATUS

A Complete Monitored Category flock gains program status based on the flock's Status Date. Once a flock is approved to participate in the program, that flock will be considered an Enrolled flock with an Status Date based on the date that the application is approved by the Board. Advancement to Certified status is based on an Enrolled flock complying with the standards in this part and maintenance of an Status Date that is greater than 5-years.

ENROLLED - A flock that has been approved to participate in the program under Section II D 1.

CERTIFIED - An enrolled flock that has participated in the program for over five years and has met the necessary requirements to progress beyond Enrolled Status.

2) GENERAL PROVISIONS

The flock owner or manager that participates in the Complete Monitored Category will agree to:

a) immediately report scrapie suspect animals and animals suspected of other neurologic and chronic debilitating (prolonged wasting) illnesses to a State or Federal Animal Health Official, or an accredited veterinarian.

b) ensure that proper tissue samples are collected and submitted for diagnostic purposes. Such animals must not be sold for breeding or slaughter purposes.

c) officially identify all animals 1 year of age or over within a flock. All animals less than 1 year of age will be officially identified when a change of ownership occurs, with the exception of those moving within slaughter channels. Official identification for the above stated animals meets the following criteria:

- ·permanent,
- ·secure,
- ·unique from a central repository, and
- ·traceable.

The types of Program approved identification are:

- ·Tamper-resistant Ear Tag,
- ·Flank or Ear Tattoo, and
- ·Electronic Identification.

A secondary form of identification may be maintained at the owner's discretion.

d) maintain records in accordance with the specific provisions of the applicable Program Status. Records must be kept for a minimum of five years after an animal dies or has otherwise been removed from the flock.

Records which must be kept on animals present in the flock at the time of initial participation:

1. Official and any secondary identification number,
2. Sex,
3. Breed,
4. Disposition--date and cause of death, if known, or movement date and to whom.
5. Progeny's Official and any secondary identification numbers and sex.
6. If available; date of birth or date of acquisition, flock of origin and date of entry, and sire and dam's official and any secondary identification.

Records to be kept on acquired or natural additions to the flock subsequent to enrollment:

1. Official and any secondary identification number,
2. Sex,
3. Breed,
4. Date of Birth, or date of acquisition,
5. The flock of origin and date of entry, and
6. Disposition--date and cause of death, if known, or movement date and to whom.
7. Sire and Dam's Official and any secondary identification numbers; and
8. Progeny's Official and any secondary identification numbers and sex.

e) allow breed associations and registries, livestock markets, and packers to disclose records to Veterinary Services representative or State Animal Health Officials. These records will be used to trace a source of exposure and other exposed animals.

f) notify the State Scrapie Certification Board about acquisitions that would lower the Status and/or Status Date of a flock, as per Section III 5, within 30 days after the animal enters the flock.

g) make animals and records available for inspection by Veterinary Services representatives, State Animal Health Officials and State Scrapie Certification Board representatives, given reasonable prior notice. The owner shall agree to have the necessary facilities and personnel available to assist in inspecting the identification of each animal and the records.

h) ensure that tissues from scrapie suspect animals, and animals suspected of other neurologic and chronic debilitating (prolonged wasting) illnesses will be submitted to an official laboratory in accordance with Section IV and Appendix I. Other tissues will be submitted at the request of the State Scrapie Certification Board or State or Federal animal health official.

3) INSPECTIONS

An authorized State or Federal Animal Health Official representatives must inspect Complete Monitored flocks every 11-13 months, based on the Enrollment Date. Inspectors will check:

·Each animal for official identification and scrapie signs; and
·Records for:
1. Completeness,
2. Accuracy, and
3. All acquisitions, departures, births, and deaths.

4) EVIDENCE OF SCRAPIE

Enrolled flocks identified as infected or source will be removed from the program and handled according to 9CFR, part 79. If an enrolled flock is deemed to be a trace or exposed flock all of the animals 18 months of age or older that die on the farm will have tissues (brain, retropharyngeal and submandibular lymph nodes) submitted for diagnostic purposes. The probable cause of death must be maintained in the records. The rate of submission will continue for three years after the date of notification that the flock was identified as a trace or exposed flock. This may be modified with an exemption granted by the Deputy Administrator of Veterinary Services. As part of the epidemiological investigation some animals in a trace or exposed flock may be deemed to be “high risk” as per 9CFR, part 79. It will be recommended that these animals be removed from the flock and not sold for breeding purposes. If current regulations mandate more restrictive actions they will take precedent over the recommendations of this program. If a preclinical diagnostic technique for screening a flock for scrapie becomes available, this method may be used to assess the risk of Scrapie infection in trace and exposed flocks.

5) ACQUISITIONS

The State Scrapie Certification Board must be notified about all acquisitions during the annual inspection process, and all acquisitions that do not meet program standards within 30 days of acquisition.

a) RAM ACQUISITIONS

Enrolled flocks may acquire breeding rams from any flock if the rams are:

- ·Officially identified
- ·Shown on the flock inventory
- ·Not born in or transited a flock when it was designated as Source, Trace, Infected or Exposed

Certified flocks can only acquire rams from other certified flocks or enrolled flocks only if they meet the above requirements. Rams cannot be commingled with other animals, except as permitted by Section III A 6.

At present, there is no scientific evidence that implicates rams as a risk for the spread of scrapie. Rams would be considered a lower risk for the spread of scrapie than ewes, but we cannot totally rule out rams as a risk of Scrapie exposure. We would recommend that producers consider risk when selecting rams from nonparticipating flocks.

b) EWE ACQUISITIONS

Enrolled flocks may acquire ewes from flocks with the same Status Date or higher. If an Enrolled flock acquires ewes from an Enrolled flock with a more recent Status Date, the Status Date of the receiving flock will become the most recent Status Date of the flocks involved. Certified flocks may purchase ewes from certified flocks, regardless of Status Date, without a change in enrollment status. The flock owner must notify the Board of acquisitions that may Change their Status Date within 30 days of acquisition.

c) PROGRAM STATUS TRANSFER WITH PURCHASED ANIMALS

A purchasing flock may retain the Status Date of acquired animals only if they:

- ·have not been commingled with nonparticipating animals; or
- ·have not been commingled with animals from a flock with a more recent Status Date.

When establishing a new flock entirely from an enrolled or certified flock, the flock of origin's Status Date will transfer to the new flock if the new flock notifies the State Board and submits an application for participation in the program within 30 days of the animal's arrival on the farm. Applications received beyond 30 days will be treated as new applicants to the Program. Animals from a higher status flock or an enrolled flock with an Status Date older than the flock of destination, will convert to the lower flock status (i.e., from certified to enrolled) with the Status Date of the flock of destination.

6) COMMINGLING

An enrolled flock's Status and Status Date will be in jeopardy if:

·ewes are commingled with animals from a nonparticipating flock or an enrolled flock with a more recent Status Date, other than limited contacts, and then returned to the original flock; or
·rams do not meet Program Standards and/or their use in nonparticipating flocks do not meet the following requirements:

1) No commingling with ewes for 30 days prior to and 60 days following lambing.
2) No housing or maintenance of the ram in lambing facilities.
3) The ram must reside in the enrolled flock other than for breeding purposes.

A Certified flock's Status and Status Date will be in jeopardy if:

·ewes are commingled with animals from enrolled or non-participating flocks; or
·rams are commingled with animals from non-participating flocks and their use in nonparticipating flocks does not meet the following requirements:

1) No commingling with ewes for 30 days prior to and 60 days following lambing.
2) No housing or maintenance of the ram in lambing facilities.
3) The ram must reside in the enrolled flock other than for breeding purposes.

7) USE OF SEMEN AND EMBRYOS

Enrolled flocks may not use germplasm from any donor found to be scrapie-positive. Enrolled or certified flocks may use semen from lower Status or nonparticipating flocks with no effect on Program Status or Status Date. The semen may not originate from:

·Infected Flocks,
·Source Flocks,
·Trace Flocks, or
·Exposed Flocks

at the time of collection. Enrolled or certified flocks may receive embryos with no effect on Program Status or Status Date if the embryos originated from:

·flocks with the same or higher Program Status or Status Date;
·A foreign country free of scrapie as designated by APHIS; or
·a flock in a foreign country that has met APHIS recognized program standards equivalent to the current Program Status.

Embryo recipient ewes must meet the Program's requirements for ewe acquisitions.

The embryo's Status is equivalent to the Status of the donor's flock on the date of implantation. The embryo's Status Date is equivalent to the Status Date of the donor's flock on the date of collection. For example, if the donor's flock had Enrolled Status and a Status Date of October, 1995, and that on the implementation day, July, 1997, the donor's flock's Status was Enrolled with a Status Date of May, 1996, the embryo's Status would be Enrolled with a Status Date of October, 1995. That embryo was eligible to enter flocks with Enrolled Status and a Status Date of October, 1995 or later. The Status and Status Date of the embryo would then convert to the Status and Status Date of the recipient upon implantation, if the ewe has a Status Date later than the Status Date of the embryo.

8) IMPORTED ANIMALS

Imported animals from foreign countries may enter the program at the appropriate level if they have an equivalent certification program recognized by APHIS, or are recognized free of scrapie by APHIS' standards. These animals cannot at any time commingle with animals of a lower Program Status.

B. SELECTIVE MONITORED CATEGORY

The Selective Monitoring Class is open to any flock, and is mainly for slaughter lamb producers who wish to allow for an additional method for Scrapie surveillance in large production flocks. Selective Monitored Category flocks would be eligible for Enrolled or Certified Status if an application to the Complete Monitored Category is made.

1) IDENTIFICATION

Participants must officially identify all male animals one year old or older.

2) ANIMAL RECORDS

Participants must keep the following records for all male animals one year and older:

1. official and secondary identification,
2. Breed,
3. Acquisition date and flock of origin, and
4. Disposition--date and cause of death if known, or date of movement and to whom.

3) INSPECTIONS

Authorized State or Federal Animal Health Officials must inspect participating flocks every 11-13 months (Status Date +/- one month). Inspectors will check:

·Each male animal one year old or older for official identification;
·Records of slaughter inspections for all cull animals;
·The flock for signs of scrapie; and
·The records for completeness and accuracy.

4) ROUTINE MONITORING FOR EVIDENCE OF SCRAPIE

These flocks will be monitored for evidence of scrapie by ONE of the following methods:

·flocks with 1000 ewes or less must submit one animal for Scrapie diagnosis as specified in Section IV and Appendix I each year. For flocks with over 1000 ewes, a submission rate of one animal per 1000 should be made. The animal(s) should be a cull ram or ewe more than two years old or routine death loss; or
·if any rams or ewes more than two years old are in the flock, and at least one of these animals die during the year, tissues must be submitted for Scrapie diagnosis as specified in Section IV and Appendix I; or

·if any animal 4 years old or older is necropsied by an accredited veterinarian, tissues will be submitted for scrapie diagnosis as specified in Section IV and Appendix I.

The Scrapie diagnostic requirement would be waived if a flock had no death/cull losses in animals more than two years old during the reporting period. All submissions of tissues for Scrapie diagnosis must be made by an accredited veterinarian or a State or Federal regulatory veterinarian.

5) SLAUGHTER INSPECTION

An accredited veterinarian will inspect ALL cull ewes in Selective Monitored flocks for clinical signs suggestive of scrapie:

·Prior to slaughter and
·While they are still identifiable to the flock of origin.

6) EVIDENCE OF SCRAPIE

Any animal(s) showing clinical scrapie signs (e.g., neurologic signs) in a Selective Monitored flock are not to be used or sold for breeding purposes. Upon death, these animals must be reported to State or Federal regulatory officials and necropsied by an accredited veterinarian or a State or Federal regulatory veterinarian with tissues submitted in accordance with Section IV and Appendix I.

·These animals shall not be used for breeding purposes or sold for slaughter.
·Enrolled flocks identified as infected or source, will be handled according to 9CFR, part 79. Upon confirmation of Scrapie, the flock's status would change to infected or source.

If a flock is deemed to be a trace or exposed flock all of the animals 18 months of age or older that die with clinical signs suggestive of Scrapie, will have tissues (brain, retropharyngeal and submandibular lymph nodes) submitted for diagnostic purposes. The probable cause of death must be maintained in the records. The rate of submission will continue for three years after the date of notification that the flock was identified as a trace or exposed flock. This may be modified with an exemption granted by the Deputy Administrator of Veterinary Services. As part of the epidemiological investigation some animals in a trace or exposed flock may be deemed to be "high risk" as per 9CFR, part 79. It will be recommended that these animals be sold for slaughter. If current regulations mandate more restrictive actions they will take precedent over the recommendations of this program.

If a preclinical diagnostic technique for screening a flock for scrapie becomes available this method may be used to assess the risk of Scrapie in the flock.

7) ACQUISITIONS AND MOVEMENTS

Selective Monitored participants:

·Must not purchase animals listed as infected or source flocks;
·Are encouraged to purchase animals from Complete Monitored flocks; and
·Must officially identify all male animals when ownership changes, except for those animals moving in slaughter channels.

8) SELECTIVE MONITORED CATEGORY STATUS MAINTENANCE

A Selective Monitored flock will maintain its status indefinitely, provided the flock continues to meet the Selective Monitored requirements, or until it enters the Complete Monitored Category.

IV. LABORATORY PROCEDURES AND TEST INTERPRETATION

A. GENERAL CONSIDERATIONS

Official laboratories will examine all Voluntary Scrapie Flock Certification Program tissues as submitted per Appendix 1. The official laboratory will report diagnostic findings to the submitter and APHIS.

B. LABORATORIES

National Veterinary Services Laboratories will assist official laboratories in ensuring quality control for the diagnosis of Scrapie.

C. DIAGNOSTIC TESTS

Official laboratories must use currently recognized procedures for:

- Examining tissues, and
- Establishing a presumptive scrapie diagnosis.

Official laboratories shall use histopathological examination such as described by L. D. Miller, et al.(1) and Race, R., et al. (2) as the primary diagnostic criteria. Official Laboratories shall submit appropriate specimens to the reference laboratory, the National Veterinary Services Laboratories, U.S. Department of Agriculture, Ames, Iowa, to confirm the presumptive diagnosis.

All diagnostic laboratories, including official laboratories, where a diagnosis of Scrapie cannot be made in animals exhibiting clinical signs suggestive of Scrapie and no other disease condition can be diagnosed, should send samples to NVSL for supplemental diagnostic tests.

The reference laboratory routinely:

- Examines brain tissue histopathologically and
- Conducts immunohistochemical surveys for prion protein (PrP^{SC}) (3)

for a final and official diagnosis. Western blot techniques or other subsequently evolving methodologies acceptable to the veterinary community may augment histopathology and immunohistochemistry in diagnosing scrapie.

(1) Miller, L.D., W. Landgraf, and W. D. Taylor. Scrapie: Procedures for laboratory diagnosis. American Association of Veterinary Laboratory Diagnosticians. 28th Annual Proceedings pp.417- 420 (1985).

(2) Race, R., B. A. Ernst, A. L. Jenny, W. D. Taylor, et al., Diagnostic Implications of Detection of Proteinase k-resistant Protein in Spleen, Lymph Nodes, and Brain of Sheep. Am J Vet Res 53:883-889 (1992).

(3) Miller, J. M., A. L. Jenny, W. D. Taylor, et al., Detection of prion protein in formalin-fixed brain by hydrated autoclaving immunohistochemistry for the diagnosis of scrapie in sheep. J Vet Diag Invest 6:366-368 (1994).

V. FLOCK INFORMATION

The Centers for Epidemiology and Animal Health (CEAH) maintain a national information data base about:

- Enrolled and Certified flocks in the Voluntary Scrapie Flock Certification Program
- Infected flocks
- Source flocks.

Interested parties may access this information 24 hours daily, 365 days per year, through dialing 1- 800-545-USDA (8732) on a touch tone phone. Select option 4 to connect with the Voluntary Scrapie Flock Certification Phone Query System. Producers may obtain more detailed information on the Phone Query System from an APHIS representative.

The National Animal Health Programs Staff prepares periodic reports from the national data base on enrolled, infected and source flocks. The following information will be made available to the public on flocks participating in the program: Name, Address, Enrollment Date and Status Date. These reports or lists are publicly available through:

- The Phone Query System
- The State animal health representative
- The APHIS representative
- The National Animal Health Program Staff at (301) 734-6954.
- The APHIS Web Site: http://www.aphis.usda.gov/vs

APPENDIX I

SPECIMEN COLLECTION AND SUBMISSION

When scrapie is suspected in a live animal, the owner shall contact a State or Federal Animal Health Official or an accredited veterinarian. The accredited veterinarian or the State or Federal veterinarian will include the following with each diagnostic submission:

·all identification devices for use in traceback
·age of animal, based on dental examination
·record breed and sex of animal
·heparinized blood sample for potential DNA testing at the producer's expense, and
·any additional samples as requested by the AVIC or State Veterinarian

BRAIN REMOVAL

The following should enable the veterinarian to submit a proper brain specimen:

1. Wear rubber gloves.
2. Cut through the atlanto-occipital joint to separate the head from the carcass.
3. Incise the skin on the midline over the poll, forehead, and nose. Reflect skin laterally to expose the skull, orbits, and caudal part of the nose.
4. Using a postmortem saw, transversely cut 1-2 cm deep across the caudal part of each orbit.
5. Cut on each side of the skull from the foramen magnum to a point 2-3 cm medial to the orbital rim, transecting the transorbital cut. Angle each cut inward at about 45 degrees from the vertical axis.
6. Insert a heavy knife or bone chisel into the transverse cut and slowly pry the skull cap up and back. Take care to prevent the attached meninges from compressing or tearing the brain parenchyma. Cut the meninges as the skull cap is removed. Scissors are more suitable than a knife for cutting these membranous attachments.
7. Cut the meninges between the cerebral hemispheres and over the cerebellum. Reflect the meninges laterally to remove them.
8. Hold the head with the nose or jaw pointing upward to allow gravity to assist in removing the brain from the cranial cavity. Cut through the brain attachments starting with the:

   ·Olfactory tracts
   ·Optic nerves and
   ·Pituitary stalk

   and work caudally through the other cranial nerve roots. Gently tease the brain out of the cranial cavity while cutting through the attachments. Allow the brain to drop gently onto a clean, dry surface.

SPECIMEN SUBMISSION

Separately bag each tissue and label each bag with owner, animal, and tissue identification.

A VS FORM 10-4 shall be completed for each sample submitted to NVSL. Place the separately bagged tissues in another bag with owner and tissue identification to facilitate shipment and ship the samples to NVSL. Remove and ship the brain with as little contamination, distortion, and laceration as possible.

Collect and send all manmade identification, a copy of the VS FORM 10-4 submission, and the heparinized blood sample and send it to the AVIC to facilitate any epidemiologic investigation that may be related to this submission.

·Collect the brain with a portion of attached anterior spinal cord.
·Divide the brain and anterior spinal cord in half longitudinally. Start the cut rostrally between the cerebral hemispheres and proceed caudally.
·If possible, perfuse one half of the brain with fixative after flushing the vascular bed with saline or water.
·Place the fixed half of the brain in at least one liter of 10 percent neutral buffered formalin solution. The optimum fixative penetration is achieved with 20-40 times the tissue volume of fixative. Changes of fixative are desirable.
·Since the fixed tissue will be used for histopathology, keep this tissue separate from the dry ice, other ice packs, or frozen tissues.
·Place the other half of the brain in a separate sealed bag with owner and tissue identification. Keep this half refrigerated with ice packs during transit to an official laboratory.
·Properly prepare and separate the formalin fixed tissue with the refrigerated tissue for shipment. Do not allow the formalin fixed tissues to freeze. Place the owner's name and animal identification on the container.
·Deliver refrigerated fresh tissue to a laboratory within 36 hours of collection. Otherwise, freeze this tissue for shipment.

APPENDIX II

SCRAPIE DISINFECTION GUIDELINES

None of the following suggested disinfection and inactivation procedures may guarantee total and complete elimination and inactivation of the infectious agent, however, based on the current information available efficiency of the methods listed below are suggested for use outside of the laboratory. Until more specific information becomes available, GOOD SANITARY PRACTICES WILL HAVE TO SUFFICE.

Pastures

·Effective inactivation of the agent will destroy the forage.
·Do not graze animals on pasture where scrapie-infected animals have lambed.

Drylot

·When practical, removing the top 1-2 inches of soil/manure will reduce contamination.
·Bury, till under, or compost the removed material in areas not accessed by domestic animals or wildlife.

Non-earth Surfaces (cement, wood, metal, tools, equipment, instruments, feed, hay, bedding, and other materials)

·Remove all organic material and compost or incinerate.
·Clean and wash surfaces and other items using hot water and detergent.
·Allow all surfaces, tools and equipment to dry completely before disinfecting and sanitizing using these suggested methods:

1. Incinerate items by high temperature incineration methods when possible.
2. Autoclave instruments, small tools, and other items at 136 degrees C for 1 hour when possible.
3. To clean dry surfaces apply a 2 percent available chlorine Solution (equivalent to about 20,000 ppm. Available chlorine: 50 oz (6 1/4 cups) chlorox in 1 gal water) at room temperature (at least 18.3 degrees F: 65 degrees C) for 1 hour.
4. For environmental purposes use this disinfection method when the above methods are not available. Expose dry surfaces by applying 1 molar solution of sodium hydroxide (approximately 4 percent solution (5 oz sodium hydroxide dissolved in l gal water) at room temperature (at least 18.3 degrees F: 65 degrees C) for at least 1 hour. Synonyms for sodium hydroxide are caustic soda, soda lye, and sodium hydrate.

APPENDIX III

EXHIBITION AND TRANSPORTATION GUIDELINES

Incomplete knowledge on scrapie transmission causes participants concern. Sheep exhibitions and transportation pose a risk for scrapie transmission. The following guidelines may lower these risks:

·Separate enrolled from nonenrolled sheep by:

1. A vacant pen; or
2. Barn Alley; or
3. Solid physical barrier

sufficient to prevent any physical contact between enrolled and nonenrolled sheep.

·Limited contacts in the show or sales ring:

1. Pose minimal risk of scrapie transmission.
2. Are contacts between animals that occur off the flock's premises and not during or immediately after lambing.
3. Do not include commingling which is where animals are grouped together with free physical contact.

·Lambing increases the exposure potential. Prevent contact with lambing ewes at exhibits or sales.

APPENDIX IV

IDENTIFICATION GUIDELINES

Official identification for certain animals in the Voluntary Scrapie Flock Certification Program meets the following criteria:

- ·Permanent
- ·Secure
- ·Unique number from a central repository
- ·Producer responsible for traceability

Program approved means of identification are:

- ·Tamper-resistant Ear Tag approved by APHIS
- ·Flank or Ear Tattoos
- ·Electronic Identification

Participants are responsible for applying official identification. Tamper-resistant ear-tag users should obtain ear-tags that are approved by APHIS and have been permanently imprinted with the flock's premises code and individual animal number.

For the purposes of premises identification, a two-letter abbreviation of the State followed by three numbers ranging from 001 to 999 should be initiated and maintained at the USDA, APHIS, VS, Area Office in a State. For example, a participating premises in the State of Alabama will be identified as AL001, AL002, etc., to AL999. If additional codes are needed, States can use an alphabetical identification system (i.e., AAA, AAB, A01, A02, etc....).

Electronic identification users should heed the following:

- ·Place implants above or dorsal to the auricular or ear cartilage
- ·When selling electronically identified animals, except to slaughter, provide an identification certificate stating:

    1. Animal's date of birth, sex, breed, registration name and number
    2. Electronic Identification number and any secondary identification
    3. Breeder's name and address

- ·Buyer of an animal with electronic identification should keep the certificate with the animal's records to document receiving electronic identification.

Ear or flank tattoo users should heed the following:

·use two separate tattoos:

1. A four-character alphanumeric premises code assigned by APHIS as explained above.
2. A legible, unique, individual, animal number.

·Apply the premises code in the right ear and individual animal number in the left ear or place both numbers in each ear or on the right flank in the wool-free area.
·Animals with breed or registry tattoos require only a premises code tattoo in the right ear or right flank.

APPENDIX V

GENETICS AND SCRAPIE

Theories on the cause of scrapie have been debated for many years and the debates still go on today. Initially, arguments over cause centered around a genetic versus infectious origin. Current information indicates that both genetics and an agent play a role in the occurrence of scrapie.

H. B. Parry felt that scrapie was an autosomal recessive genetic disease which was not naturally infectious and that it arose spontaneously in certain genotypes. He did concede that affected animals harbored a transmissible agent which was infectious by artificial routes. Data accumulated from 1,400 cases appeared to support his theory (Parry, 1964). However, recent work published by Hunter and colleagues (Hunter et. al., 1997b) shows that genotypes considered the most likely to give rise to spontaneous scrapie also exist in New Zealand and Australia. Both countries are considered by most to be free of scrapie. There is information to suggest that scrapie was a naturally occurring contagious disease which was caused by an infectious agent (Brotherson et. al.,1968; Dickinson et. al., 1974; Hourrigan et. al., 1979). However, the precise mechanism of natural transmission is not well understood.

Current information indicates that both genetics and an agent play a role in the occurrence of scrapie. It is evident there could be a wide variation in the clinical manifestations as well as the pattern and intensity of histopathological lesions associated with scrapie and related transmissible spongiform encephalopathies. It is now well established that the phenotypic expression of disease is a direct result of host-agent interaction. Some aspects of pathogenesis can differ, depending upon the interaction of agent strain, host genotype, route of injection, and dose of agent. If any one of these parameters are altered, so are some of the phenotypic appearances of disease. These distinct phenotypes must result from an interaction at the molecular level between host and scrapie strain.
Characteristic of this disease is the control of the incubation period through host gene loci such as Sip (scrapie incubation period) in sheep and Sinc (scrapie incubation) in mice. It is likely that the PrP gene and the genes controlling scrapie incubation periods (Sip and Sinc) are the same (Carlson et. al., 1986; Hunter et. al., 1987; Hunter et. al., 1989; Westaway et. al., 1987).

In sheep, two phenotypes of the Sip gene, which correspond to the PrP gene were identified in an experimental flock of Cheviot sheep. The phenotypes sA (short incubation allele) and pA (prolonged incubation allele) are associated with amino acid changes at codon 136 (Hunter et al 1989) Sheep carrying either the 136 Valine/Valine (sA/sA) or 136 Valine/Alanine (sA/pA) genotypes develop clinical disease with strain A group scrapie isolate. Since this initial finding other polymorphisms found at codon 154 and 171 have been associated with clinical scrapie. Other genes or loci may yet prove to be important, however as more genotyping is done the picture may become more complex.

At codon 136, the nucleotide sequence codes for either valine or alanine.
At codon 154, the nucleotide sequence codes for either histidine or arginine.
At codon 171, the nucleotide sequence codes for either glutamine, arginine, or histidine.

Amino acid changes at codons 154 and 171 modulate the incubation time in the susceptible sheep. Cheviot sheep with the genotype 136 Alanine/Alanine (pA/pA) do not exhibit evidence of clinical disease after exposure to strain A scrapie (Hunter et. al., 1996, Maciulus et. al., 1992, Goldmann et. al., 1991, Goldmann et. al., 1990). However, Cheviot sheep with 136 Alanine/Alanine genotype develop clinical scrapie after exposure to strain C group scrapie if they carry the amino acid glutamine at codon 171 (Foster & Dickinson, 1988; Goldmann et. al., 1994a, Goldmann et. al., 1994b).

Suffolk sheep rarely carry the 136 Valine allele. In this breed, natural and experimental scrapie is associated with 171 Glutamine/Glutamine (Westaway et. al., 1994, O'Rourke et. al., 1996). With very few exceptions, naturally infected sheep of a number of breeds in the US, UK, Europe and Japan carry either 136 Valine (136 Valine/Valine or 136 Valine/Alanine) or 171 Glutamine/Glutamine(QQ) (Belt et. al., 1995, Clouscard et. al., 1995, Hunter et. al., 1993, Hunter et. al., 1994, Ikeda et. al., 1995, Laplanche et. al., 1993a, 1993b; Westaway et. al., 1994, O'Rourke et. al., 1996). There has been only one report of a scrapie-affected Suffolk carrying 171 Arginine/Arginine (RR) (Ikeda et. al., 1995). There have been 3 reports of Suffolks carrying 171 Arginine/Glutamine (QR) which have developed clinical scrapie (Ikeda et. al., 1995; Hunter et. al., 1997a). In sheep there have also been other PrP gene polymorphisms identified, however it appears as the ones identified at codons 136,154 and 171 play the largest role in regards to scrapie (Hunter et. al., 1996). The clinical and pathological heterogeneity observed following infection appears to be controlled by both the particular scrapie strain and the host PrP genotype.

There are still many questions which must be answered before the role of genetics in relationship to scrapie susceptibility is fully understood. Some of these are as follows:

1. Do certain genotypes fully prevent scrapie infection or merely protect against the clinical manifestation of the disease?
2. Is there a carrier state wherein clinically normal animals are shedding the agent and are a risk to other susceptible sheep?
3. If a flock was bred to be "resistant" to a certain strain of scrapie and another strain was introduced, would a vast majority of the animals succumb to the disease?

The PrP gene may be responsible for directing the infectious agent to specific target sites both within and outside of the central nervous system (Bruce et. al., 1991; Scott et. al., 1992).

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